

# **REMARKS**

In view of the following remarks, the Examiner is requested to allow Claims 21-34 and 42-43, the only claims pending and under instant examination.

## ***Claim Rejections – 35 U.S.C § 112, first paragraph***

Claim 43 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleges that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action, pg. 2, section 3.

The Applicants respectfully disagree. Claim 43 was previously amended to include the element that the “extension product is not separated from said single stranded template nucleic acid.” The Examiner alleges that there is no support that the extension product is not separated from the single stranded template nucleic acid. Office Action, pg. 3, lines 6-8. The Applicants respectfully refer the Examiner to the instant Specification, on page 5, lines 22-23, which states as follows:

“the excess cdNTPs can be washed away from the single stranded DNA without dislodging the hybridized, extended primer.” (emphasis added).

Further support for this amendment may be found at least, for example, on page 8, lines 10-14 of the instant Specification, which states as follows:

“As indicated above, prior to cleavage of the tag from the extended base on the DNA template, the excess, unincorporated cdNTPs are preferably removed from the extension reaction. According to the invention, the tags may be removed by any of a variety of washing or rinsing procedures that separate the excess, unincorporated dNTPs from the extended DNA template.” (emphasis added).

As such, it is submitted that the previously submitted amendment to Claim 43 does not introduce new matter to the application, and withdrawal of the 35 U.S.C. § 112, first paragraph, rejection of Claim 43 is requested.

***Claim Rejections – 35 U.S.C. § 102***

Claims 21-31, 33-34, and 42-43 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Schmidt et al. (WO 99/02728).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 21 is directed to a method of determining a nucleic acid sequence, and includes the element of "cleaving said 3' cleavable tag from said extension product to produce a cleaved tag, not bound to said at least one complementary nucleotide, and an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence".

Accordingly, the term "extension product" is defined in the claims as the complementary sequence that results from hybridizing a primer nucleic acid to a single stranded nucleic acid template and extending this primer by at least one nucleotide base (complexed with 3' cleavable tag), the base being complementary to the single stranded template.

In contrast, Schmidt teaches "providing at least one DNA single-stranded template primed with a primer", followed by "generating the population of DNA fragments from the at least one template". Schmidt, pg. 2, lines 25-29. Schmidt further discloses "separating the fragments on the basis of their length", and then subsequently "cleaving each fragment in a mass spectrometer to release its mass label". Schmidt, pg. 2, lines 1-7. Finally, Schmidt discloses "determining each mass label by mass spectrometry". Schmidt, pg. 2, line 8. Hence, in the method disclosed by Schmidt, prior to cleavage and detection of the mass label, the DNA fragments are dissociated and separated from the DNA single-stranded template.

Consequently, Schmidt does not teach the element of "cleaving said 3' cleavable tag from said extension product to produce a cleaved tag, not bound to

said at least one complementary nucleotide, and an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence", as claimed by the Applicants.

The Examiner further states that, "The response discussed the definition of the extension product. The response further argues that Schmidt et al. teach dissociation of the extension products, which are washed in a single step. However, this limitation discussion herein is not recited by the claims." Office Action, pg. 4, lines 14-17.

The Applicants respectfully disagree. As explained above, the instant invention includes the element of "an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence". Thus, the term "extension product" is defined in the claim to include "at least one complementary nucleotide hybridized to said template nucleic acid sequence".

Thus, contrary to the Examiner's assertions, at least one element which distinguishes the instant claims from the teachings of Schmidt is recited by the instant claims, namely "cleaving said 3' cleavable tag from said extension product to produce a cleaved tag, not bound to said at least one complementary nucleotide, and an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence".

Therefore, Schmidt cannot anticipate the claimed subject matter because it fails to teach every element of the rejected claims. Hence, the Applicants respectfully request that the rejection of claims 21-31, 33-34 and 42-43 under 35 U.S.C. § 102(b) be withdrawn.

***Claim Rejections – 35 U.S.C. § 103***

Claim 32 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schmidt et al. (WO 99/02728) in view of Cheeseman et al. (U.S. Patent No. 5,302,509).

As set forth above, Schmidt is deficient in that it fails to disclose the claimed element of "cleaving said 3' cleavable tag from said extension product to produce a cleaved tag, not bound to said at least one complementary nucleotide, and an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence". The Applicants submit that Schmidt is also deficient in that it fails to suggest all the elements of the Applicants claims because in the method disclosed by Schmidt, prior to cleavage and detection of the mass label, the DNA fragments are dissociated and separated from the DNA single-stranded template. Thus, Schmidt does not disclose or suggest the element of "cleaving said 3' cleavable tag from said extension product to produce a cleaved tag, not bound to said at least one complementary nucleotide, and an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence", as claimed by the Applicants.

Cheeseman was cited solely for its alleged disclosure of a fluorescent cleavable tag. Consequently, Cheeseman fails to remedy the deficiencies of Schmidt. Therefore, the cited combination of Schmidt and Cheeseman does not disclose or suggest all the elements of Claim 32, and the Applicants respectfully request withdrawal of this rejection.

**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 327-3400.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10010632-3.

Respectfully submitted,

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